NEW JERSEY DEPARTMENT OF HEALTH AND SENIOR SERVICES
DRUG UTILIZATION REVIEW COUNCIL

Telephone: (609) 292-4029 Fax: (609) 292-8713
Website: www.state.nj.us/health/mgmt/drugutilization

Mailing Address:
Drug Utilization Review Council
Room 501
PO Box 360
Trenton, NJ 08625-0360

Overnight Services (UPS, FedEx):
Drug Utilization Review Council
Room 501
369 John Fitch Plaza
Trenton, NJ 08611

DRUG PRODUCT REGISTRATION

ONLY THE MANUFACTURERS OF APPROVED PRODUCTS MAY BE LISTED IN THE FORMULARY

New Jersey State Law (N.J.S.A. 24:6E-1 et seq.) created a Drug Utilization Review Council for the purpose of preparing a List of Interchangeable Drug Products ("generic formulary"). The criteria on which acceptable generics are judged are given at N.J.A.C. 8:70. The information requested below, as well as information we may later request, will determine whether your company's products will be listed in the List of Interchangeable Drug Products. Under State Law, any manufacturer may request that a drug product be added to, or removed from, the Formulary.

INSTRUCTIONS:

- **Applications must be typewritten and notarized; use this form or an exact copy. *ANSWER ALL QUESTIONS*.**
- **One application per dosage form. If this product has several strengths, they may be listed on one application. Do not submit additional applications for different package sizes.**
- **Address applications and questions to the address on the letterhead.**
- **You must submit a copy of your most recent FDA Form 483 or 482 pertinent to the manufacture site of this product. The first page is sufficient.**
- **You must submit an FDA approval letter, if applicable.**
- **You must submit copies of your labels that indicate the manufacturer's name.**
- **If a biostudy is required, submit 2 copies of your biostudy summary with completed Biodata Analysis forms. Each copy of the study must be bound separately in a suitable 3-ring binder.**
- **As proof of availability to New Jersey consumers, you must submit a copy of invoices indicating sale to wholesalers and distributors who transact business with New Jersey pharmacies. See Question #18.**
- **If additional space is required, please attach documents and indicate on the application.**

1. Name of Manufacturer	2. Date of Application
3. Mailing Address of Manufacturer	4. Address of Manufacturing Site (if different)
5. Name of Contact Person (for clarification of this application)	6. Contact's Telephone Number
7. Brand for which the above is a substitute:	8. Dosage Form:

9. Generic name and strengths of drug submitted for inclusion in the Formulary for single ingredient items **OR** Name and amount of each active ingredient:

_____

_____

_____

_____

_____

This Application is valid for 1 year from the date published in the New Jersey Register.

DRUG PRODUCT REGISTRATION, CONTINUED

10. Does each batch of this drug conform to official standards prior to being marketed?
☐ Yes ☐ No

11. Date manufacturing site for this product was last inspected by FDA for CGMP compliance

12. Do you have FDA approval to market this product?
☐ Yes ☐ No

13. Is this product:
Manufactured under an ANDA? ☐ Yes ☐ No
Manufactured under the NDA? ☐ Yes ☐ No

14. Have bioequivalency studies been submitted to the FDA?
☐ Yes ☐ No If No, supply details or indicate FDA reference if applicable:

15. Has this drug product been involved in any litigation, including patent suits, in the last 2 years?
☐ Yes ☐ No (If yes, attach particulars)

16. Does the name of the manufacturer appear on all distributors' labels? Supply label of most commonly used package sizes.
☐ Yes ☐ No

17. Is this product currently marketed and available to pharmacies?
☐ Yes ☐ No If not, when will it be launched?

18. List four (4) distributors, at least one of which is a wholesaler, who now carry or will carry this product and do business with pharmacies in New Jersey. Supply invoices as proof of availability (prices may be redacted).

_____ ☐ Now Carry ☐ Will Carry
_____ ☐ Now Carry ☐ Will Carry
_____ ☐ Now Carry ☐ Will Carry
_____ ☐ Now Carry ☐ Will Carry

19. National Drug Code

20. Usual Cost to Pharmacies (AWP/100 or specify)

I agree to inform the New Jersey Department of Health and Senior Services in writing of any changes in formulation or product status, manufacturing site, manufacturer name or other information as described herein, within 30 days of such change, and do certify that the information submitted is, to the best of my knowledge, correct and that this product is not now in violation of either Federal or State Law.

Please notarize individually below:

Subscribed and sworn to before me this

_____ day of _____, 20 ____

_____
Signature

_____
Name

_____
Title

OC-42
AUG 02